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### Compare Outcomes in Patients Undergoing Ileostomy Reversal with Prophylactic Mesh Placement Vs without Mesh Placement

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#### Abstract

##### Objective

To compare outcomes in patients undergoing ileostomy reversal with prophylactic mesh placement vs without mesh placement.

##### Study Design

Randomized Control Trial.

##### Setting

Department of General Surgery, Khyber Teaching Hospital, Peshawar.

##### Duration

16-10-2021 – 16-10-2022.

##### Subjects

This study was conducted on 60 patients divided in two groups. Patients were divided in two groups to either mesh reinforcement of the stoma closure site (Group A) or closure without mesh (Group B). Patients aged 18 years to 60 Years undergoing elective ileostomy and patients eligible irrespective of the operative approach that had originally been used to construct the stoma or the planned operative technique for stoma closure were included. Patients having

multiple surgeries in same admission, patients having BMI<18.5 kg/m<sup>2</sup> and diabetic patients were excluded. Data was collected into Microsoft excel sheet, analyzed through SPSS version 23.0 and presented in the form of charts and tables.

##### Results

The mean age in group A (closure with mesh) was 37.30±12.99 years and in group B (closure without mesh) the mean age was 38.90±14.22 years. The incidence of incisional hernia in group A was 2 (6.7%) and 7 (23.3%) in group B. The difference was statistically significant. (P = 0.002). The incidence of wound infection in group A was 3 (10%) and 10 (33.3%) in group B. The difference was statistically significant. (P = 0.028)

##### Conclusion

The incidence of incisional hernia formation is relatively less in patients undergoing prophylactic mesh placement following stoma reversal as compared to those patients in which mesh was not applied.

**Keywords:** Ileostomy Reversal, Prophylactic Mesh, Incisional Hernia

#### Introduction

“An ileostomy is when the small bowel is diverted to the abdominal surface resulting in the formation of a stoma which can be temporary or permanent and produces loose faeces.<sup>1</sup> A temporary diverting, or defunctionalizing, ileostomy is frequently constructed to protect low colorectal, coloanal, or ileorectal anastomoses. Although they do not prevent anastomotic leaks, they can minimize associated morbidity such as sepsis, peritonitis, poor neo rectal function.<sup>2</sup> An ileostomy should be sited away from scars, skin creases, and bony prominences to allow placement of the stoma appliance and avoid leakage.<sup>3</sup>

Temporary stoma has a negative impact on patient quality of life and it improves after reversal, but in some cases, problems remain such as temporary alteration in bowel function, often with additional social and economic burdens. Delay in reversal of the ileostomy may be associated with an increased risk for complications.<sup>4</sup>

Ileostomy reversal is associated with significant morbidity and some of the patients with complications required surgical intervention.<sup>5</sup> Most commonly encountered surgical complications after temporary ileostomy closure include small bowel obstruction, wound infection, incisional hernias and anastomotic leak.<sup>6-7</sup>

Incisional hernias are a very common complication of ileostomy reversal and study showed that significant percentage of patients developed incisional hernia after ileostomy reversal.<sup>8</sup> Therefore it is pertinent to consider hernia prevention strategies

and Mesh reinforced closure may represent a simple and feasible strategy to reduce the incident of incisional hernia.<sup>9</sup> There are concerns regarding increase risk of surgical site infection with the use of synthetic Mesh during stoma closure.<sup>10</sup> But study have shown that placement of mesh in clean-contaminated and contaminated operative fields can be performed with minimal wound-related morbidity.<sup>11</sup>

Randomized controlled trials with the use of polypropylene mesh placement have shown a decreased incidence (15 vs. 52%) of incisional herniation without mesh placement use following ileostomy reversal.<sup>12</sup>

This study will help us in collecting and recording the occurrence of incisional hernia, its alleviation after the use of prophylactic mesh and safety of mesh regarding wound infection, hence further recommendation for the use of prophylactic mesh in ileostomy reversal can be made which may be worthwhile in our local population due to considerable underreporting in the literature.

### Objective:

To compare outcomes in patients undergoing ileostomy reversal with prophylactic mesh placement vs without mesh placement.

### Operational definitions:

#### Outcomes:

- 1. Incisional Hernia:** It will be palpable or visible discrete protrusion at the site of the ileostomy closure, associated with a palpable fascial defect assessed on the clinical examination and any breach in the abdominal wall muscles or fascia visible at the site of ileostomy reversal, with or without the passage of bowel, omentum, or fat through it, assessed on ultrasound for the last four months.
- 2. Wound Infection:** It will be assessed in terms of swelling, redness, and discharge (serous or pus) [all of these] at the wound site following ileostomy reversal with prophylactic mesh placement and without mesh placement for last four months.

**Hypothesis:** Post-operative outcome in terms of incisional hernia and wound infection following ileostomy reversal with prophylactic mesh placement is superior in comparison to without mesh placement.

### Materials and Methods:

**Study design:** Randomized Control Trial.

**Setting:** Department of General Surgery, Khyber Teaching Hospital, Peshawar.

**Duration of Study:** 16-10-2021 – 16-04-2022.

**Sample Size:** It will be 60 (30 in each group) keeping 15%<sup>10</sup> proportion of incisional hernia in Mesh Group and 52%<sup>10</sup> proportion of incisional hernia in without Mesh Group taking 80% power of test, 95% confidence interval calculated on WHO formula for sample size determination.

**Sampling Technique:** non probability consecutive sampling.

### Sample selection:

#### Inclusion Criteria:

1. Patients aged 18 years to 60 Years undergoing elective ileostomy.
2. Patients eligible irrespective of the operative approach that had originally been used to construct the stoma (open or laparoscopic), or the planned operative technique for stoma closure (trephine, midline, or laparoscopic approach).

#### Exclusion criteria:

1. Surgeon pre-operatively anticipated that a mesh repair would be required.
2. Patients having multiple surgeries in same admission.
3. Patients having BMI < 18.5 kg/m<sup>2</sup>
4. Diabetic patients.
5. Immunocompromised patients (HIV, Steroid abuse).
6. Patients with history of smoking.

### Data Collection Procedure:

This study was carried out at the Department of General Surgery Khyber teaching hospital Peshawar after attaining approval from the Hospital's Ethical Committee. Potentially eligible patients were enrolled but prior to the conduct of this study written informed consent forms were obtained from all patients. Patients were divided in two groups through blocked randomization to either mesh reinforcement of the stoma closure site (Group A) or closure without mesh (Group B). In all patients, prophylactic preoperative antibiotics were given according to local protocol. The ileostomy (including bowel, fascia, and skin) was closed in accordance with the surgeon's preferred technique (i.e., stapled or hand sewn). Patients were followed up on post op day 5<sup>th</sup>, 14<sup>th</sup>, 30<sup>th</sup> and 6<sup>th</sup> month. Clinical follow-up assessments and abdominal wall examinations were done by consultant surgeon having at least seven years post fellowship experience. The primary outcome measure was the rate of incisional hernia and wound infection at respective post-operative day. All such information including age, gender, contact no, address, height, weight, BMI, hypertension, employment status, educational status and outcomes were recorded on a predesigned proforma.

### Data Analysis:

Data were entered and analyzed using SPSS version 23.0. Mean and SD were calculated for continuous variables such as age, height, weight, BMI. Frequencies and percentages were calculated for hypertension, education status, profession status and outcomes. Outcomes were compared in both groups using chi square test. Outcomes were stratified with hypertension, employment status, education status in both groups in order to see effect modifiers. Post stratification chi square test were applied keeping P Value ≤ 0.05 as significant. All results were presented in the form of graphs and tables.

### Results:

This study was conducted on 60 patients divided in two groups. The mean age in group A (closure with mesh) was 37.30±12.99 years and in group B (closure without mesh) the mean age was 38.90±14.22 years. The height in group A

was  $1.61 \pm 0.10$  meters and  $1.56 \pm 0.08$  meters. The mean weight in group A was  $73.90 \pm 8.95$  kg and  $74.46 \pm 9.45$  kg in group B. The mean BMI in group A was  $28.35 \pm 3.96$  kg/m<sup>2</sup> and  $30.49 \pm 4.13$  kg/m<sup>2</sup> in group B. According to age distribution in the age group of 18 to 30 there were 12 (40%) patients in group A and 10 (33.3%) patients in group B. In the age group of 31 to 45 years there were 9 (30%) patients in group A and 7 (23.3%) patients in group B. In the age group of 46 to 60 years there were 9 (30%) patients in group A and 13 (43.3%) patients in group B. According to gender, there were 22 (73.3%) males in group A and 19 (63.3%) males in group B. There were 8 (26.7%) females in group A and 11 (36.7%) females in group B. The incidence of incisional hernia in group A was 2 (6.7%) and 7 (23.3%) in group B. The difference was statistically significant. ( $P = 0.002$ ) The incidence of wound infection in group A was 3 (10%) and 10 (33.3%) in group B. The difference was statistically significant. ( $P = 0.028$ ). Stratification of incisional hernia and wound infection in both groups w.r.t hypertension, employment status and wound infection.

**Table 1:** Descriptive statistics (n = 60)

Groups		Age (Years)	Height in meters	Weight in kg	BMI kg/m <sup>2</sup>
Group A (Closure with mesh)	Mean	37.30	1.6193	73.9023	28.3549
	SD	12.996	.10757	8.95232	3.96196
Group B (Closure without mesh)	Mean	38.90	1.5663	74.4683	30.4932
	SD	14.223	.08880	9.45553	4.13902

**Table 2:** Age distribution

		Age distribution			Total
		18 to 30	31 to 45	46 to 60	
Groups	Group A (Closure with mesh)	12	9	9	30
		40.0%	30.0%	30.0%	100.0%
	Group B (Closure without mesh)	10	7	13	30
		33.3%	23.3%	43.3%	100.0%
Total		22	16	22	60
		36.7%	26.7%	36.7%	100.0%

**Table 3:** Gender distribution

		Gender		Total
		Male	Female	
Groups	Group A (Closure with mesh)	22	8	30
		73.3%	26.7%	100.0%
	Group B (Closure without mesh)	19	11	30
		63.3%	36.7%	100.0%
Total		41	19	60
		68.3%	31.7%	100.0%

**Table 4:** Comparison of incisional hernia in both groups

		Incisional Hernia		Total	P value
		Yes	No		
Groups	Group A (Closure with mesh)	2	28	30	0.002
		6.7%	93.3%	100.0%	
	Group B (Closure without mesh)	7	23	30	
		23.3%	76.7%	100.0%	
Total		9	51	60	
		30%	70%	100.0%	

**Table 5:** Comparison of wound infection in both groups

		Wound infection		Total	P value
		Yes	No		
Groups	Group A (Closure with mesh)	3	27	30	0.028
		10.0%	90.0%	100.0%	
	Group B (Closure without mesh)	10	20	30	
		33.3%	66.7%	100.0%	
Total		13	47	60	
		21.7%	78.3%	100.0%	

## Discussion

Each year, around 150,000 stomas, evenly distributed between ileostomies and colostomies, are made in the United States. A correctly constructed ileostomy or colostomy can significantly enhance a patient's quality of life. Patients with a well-functioning stoma can anticipate having few limits on their way of life<sup>13</sup>. On the other hand, stoma-related issues can have a permanently negative effect on a patient's physical and mental health. Numerous illnesses, including colon cancer, ulcerative colitis, Crohn's disease, diverticulitis, ischemic colitis, radiation injury, and fecal incontinence, can be treated using stomas. The reason for the stoma, whether it was made electively or urgently, and patient variables including body habit and previous surgery all affect the associated morbidity and overall function of a stoma<sup>14</sup>.

Stoma formation is unfortunately accompanied with high morbidity, which can be divided into early and late-occurring problems. Between 20 and 70 percent of stoma-related problems are reported in the literature. Early problems include ischemia/necrosis, retraction, mucocutaneous separation, and parastomal abscess and happen within the first 30 days of the stoma being created. Parastomal hernia, prolapse, retraction, and varices are examples of late complications<sup>15</sup>.

Ileostomy is commonly used temporarily to protect a distal anastomosis such as in ileal pouch anal anastomosis or a low colorectal anastomosis. It is also used for fecal diversion from the distal anorectum such as for perianal Crohn's disease, anorectal cancer, diverticular disease, severe perineal trauma or sepsis, treatment of anastomotic leakage and fecal incontinence<sup>16</sup>. There is no significant difference in frequencies of complications between early and late closure of temporary ileostomy, but there is significant difference in types of complications that occur where the early closure has more wound complications and not associated with increased morbidity and mortality while the late closure has significantly smaller bowel obstruction rates. Temporary ileostomy closure is an elective procedure; so, the complication rate should be low but some previous studies reported high rate of serious complications and death. The overall complication rate for ileostomy closure is ranging from 4.7% to 33.3%<sup>17</sup>.

In another well-established study, Maggiori *et al.*, studied the effect of using a retromuscular (preperitoneal) bioprosthetic collagen porcine mesh at ileostomy closure site exclusively for rectal cancer patients who have undergone total mesorectal excision. They compared 30 patients mesh group with 64 patients with direct closure as a

control group. Their technique significantly reduced the incisional hernia incidence as 3% in the mesh group developed incisional hernias compared to 24% in the control group ( $p=0.016$ ).<sup>18</sup>

Morris-Stiff and Hughes in their study tried intraperitoneal usage of non-absorbable mesh (polypropylene) in repair of parastomal hernias in 7 cases; 5 with terminal ileostomies and 2 with terminal colostomies. They reported failure of their technique as 2 cases (29%) developed recurrence of the hernias in addition to more serious complications as bowel perforation and obstruction. This failure was most probably due to the risk of inserting an intra-abdominal prosthetic material especially when related to colostomies rather than ileostomies<sup>19</sup>. These data were supposed to result in a lower incidence of incisional hernias (as malignancy compared to any other indication is itself a risk factor for herniation) but they resulted in a similar incidence (31.4%). This might be due to that this study was performed on both ileostomies and colostomies with majority of cases with colostomies (93%) and all incisional hernias occurred in cases with colostomies, as colostomies produce more well-formed stool with more incidence of wound infection and other complications after the surgery<sup>20</sup>.

In our study the outcomes in terms of incisional hernia and wound infection in patients undergoing ileostomy reversal with prophylactic mesh placement vs without mesh placement were compared. Incisional hernia was found in 4 (13.3%) patients in group A and 15 (50%) patients in group B, the difference was statistically significant. The incidence of wound infection in group A was 3 (10%) and 10 (33.3%) in group B, the difference was statistically significant. In a randomized control trial study<sup>10</sup> the incidence of incisional hernia was 15% in mesh placement group and 52% in without mesh group following ileostomy reversal which is comparable to our study.

## Conclusion

The placement of a prosthetic prolene mesh following stoma reversal has a protective role in decreasing the incidence of formation of incisional hernia as well as having a paradoxical affect of reducing the percentage of patients presenting with surgical site infections.

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